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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,222	09/08/2003	Morton M. Mower	06809.0030-00000	1067

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,222

Applicant(s)

MOWER, MORTON M.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04112006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show element 140 in Figure 1 as described in the specification and noted in the figure. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities: "the" should be inserted between "of" and "heart" in paragraph 060.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 24-45 and 48-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims specify stimulating the heart from locations "in the left ventricle". Applicant discloses that "installing a similar lead into the left ventricle may create a danger to the patient due to the possibility of a thrombus being generated", and further discloses an exemplary embodiment in Fig. 4 in which the left ventricular lead is placed "through the superior vena cava...into the coronary vein" (par. 059), "in the interventricular septum" (par. 060), or "outside of [the] heart in the epicardial wall" (par. 060); but makes no mention of placing the lead *in* the ventricle (i.e. the actual interior blood-containing chamber). It is unclear whether applicant is claiming electrodes placed in the ventricle, on the ventricle, or both. Examiner is interpreting the claims to be directed to electrodes placed on the ventricles, as is customary in the art, as claimed in claim 52, and described in the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 23 and 45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims comprise electrodes implanted in the heart. This implies that the invention comprises a portion of the human anatomy, which is non-statutory subject matter. It is suggested that applicant claims electrodes "adapted to be" implanted in the heart.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 4-12, 18-26, 29-32, 35, 41, 42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Cohen (5,174,289).
9. In regards to claims 1, 19, 20 and 23, Cohen discloses a device/method comprising endocardially receiving signals from the heart, determining the progress of contraction, and stimulating a chamber of the heart at a plurality of locations based on the progress (claim 1).

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10. In regards to claim 2, atrial depolarization signals are sensed (col. 21, line 1).

11. In regards to claims 4 and 5, ventricular depolarization signals are sensed (col. 21, line 1) from multiple locations (col. 19, line 51).

12. In regards to claim 6, two signals are analyzed and the delay between them is determined (claim 29). It is inherent that the delay between senses is determined because a pace is initiated if a delay interval between senses is exceeded. Therefore, the delay would have to be sensed to determine if the delay interval is exceeded.

13. In regards to claims 7 and 8, a stimulation signal is applied at a first site and a second signal is selectively applied to a second location if an intrinsic electrical threshold is not exceeded (claim 29).

14. In regards to claim 9, the second signal can be applied simultaneously with the first (col. 19, line 28).

15. In regards to claims 10, 11 and 12, the stimulated locations are along a short axis (Fig. 28, elements 33-32) and a long axis (Fig. 28, elements 33-30) of the heart chamber, and at least three locations are stimulated (Fig. 28).

16. In regards to claims 21 and 22, the signal voltage and pulse width are variable (col. 19, line 7).

17. In regards to claims 24 and 25, Cohen's invention stimulates a plurality of locations in and on the left ventricle based on the timing of the received signals and the progress of contraction (Fig. 11).

18. In regards to claims 29-32, 35, 41, 42, and 44, left ventricular epicardial electrodes are used to perform the disclosed method above (col. 24, line 17).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claim 3 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen. Cohen discloses that his invention can be applied to the atrial chambers as well as the ventricular chambers (col. 24, line 25). Alternatively, it is well known in the art to sense signals from multiple areas of the atria to more vividly sense depolarization of the chamber. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cohen's invention by sensing from multiple locations in the atrium to more vividly sense depolarization of the chamber.

21. Claims 27, 33, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Helland (5,385,579). Cohen discloses the invention using epicardial electrodes except for providing epicardial electrodes implanted in the epicardial wall. Helland teaches of epicardial electrodes implanted in the epicardial wall to provide better anchoring. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Cohen's invention with electrodes implanted in the epicardial wall to provide better anchoring.

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22. Claims 13, 14, 17, 36, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Prystowsky et al. (4,554,922). Cohen discloses the essential features of the claimed invention except for applying either an anodal or cathodal sub-threshold pre-excitation voltage with a current of about 10 mA.

Prystowsky et al. teach of applying a sub-threshold pre-excitation voltage of about 10 mA (col. 5, line 48) to inhibit arrhythmic beats (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Cohen's invention with a sub-threshold pre-excitation voltage of about 10 mA to inhibit arrhythmic beats.

23. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Prystowsky as applied to claim 13 above, and further in view of Altman (5,551,427). The modified invention of Cohen in view of Prystowsky discloses the essential features of the claimed invention except for an electrode implanted in the interventricular septum. Altman teaches of implanting a septal electrode using a helical wire to provide better fixation and stimulation of the left ventricle. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention taught by Cohen in view of Prystowsky by implanting the electrode in the interventricular septum, using a helical wire, to provide better fixation and stimulation of the left ventricle.

24. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Smits (4,641,656). Cohen discloses the essential features of the claimed invention except for providing an electrode in the coronary vasculature. Smits teaches

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of providing an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle (Fig. 15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Cohen's invention with an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle.

25. Claim 34, 38, 39, 45, 46, 47, 51, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Smits, and further in view of Altman. Cohen discloses the essential features of the claimed invention except for providing an electrode in the coronary vasculature and implanting an electrode in the interventricular septum. Smits teaches of providing an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle, and Altman teaches of implanting a septal electrode using a helical wire to provide better fixation and stimulation of the left ventricle. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Cohen's invention with an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle and a septal electrode implanted using a helical wire to provide better fixation and stimulation of the left ventricle.

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26. Claims 48-50, 53, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen in view of Smits, Altman, and Prystowsky et al. Cohen discloses the essential features of the claimed invention except for applying a pre-excitation voltage to the stimulation site, providing an electrode in the coronary vasculature and implanting an electrode in the interventricular septum. Prystowsky et al. teach of applying a sub-threshold pre-excitation voltage to inhibit arrhythmic beats, Smits teaches of providing an electrode in a coronary vein to allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle, and Altman teaches of implanting a septal electrode using a helical wire to provide better fixation and stimulation of the left ventricle. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Cohen's invention by applying a pre-excitation voltage to the stimulation site, providing an electrode in the coronary vasculature and implanting an electrode in the interventricular septum to inhibit arrhythmic beats, allow multi-site, cross-ventricular sensing and stimulation of the left ventricle to provide a more localized electric field to be sensed and applied to the left ventricle, and provide better electrode fixation and stimulation of the left ventricle.

Response to Arguments

27. Applicant's arguments filed 4/11/2006 have been fully considered but they are not persuasive.

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28. In regards to the rejection of claims 24-45 and 48-54 under 35 USC 112(2), Applicant argued that Examiner's interpretation of the claims reciting leads placed "around or on the left ventricle" is incorrect because the exemplary embodiment shown in Fig. 4 shows a lead "in the left ventricle" and the claim 52's recitation of "in one of the coronary sinus, a coronary vein in the left ventricle, the interventricular septum, or in an epicardial wall of the left ventricle" only further limits "in the left ventricle". However, the claims are still deemed vague because the embodiment shown in Fig. 4 is only described as having the lead placed "through the superior vena cava...into the coronary vein" (par. 059), "in the interventricular septum" (par. 060), or "outside of [the] heart in the epicardial wall" (par. 060); but makes no mention of placing the lead *in* the ventricle (i.e. the actual interior blood-containing chamber). Furthermore, claim 52 cannot merely further limit claim 51 because placement "in the left ventricle" and "in one of the coronary sinus, a coronary vein in the left ventricle, the interventricular septum, or in an epicardial wall of the left ventricle" are mutually exclusive, therefore rendering the claim vague. The lead cannot be placed both *in* the ventricle (i.e. the blood-containing chamber) and "in one of the coronary sinus, a coronary vein in the left ventricle, the interventricular septum, or in an epicardial wall of the left ventricle" simultaneously.

29. In regards to the 35 USC 101 rejection of claims 23 and 45, "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter. Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable

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rejections under 35 U.S.C. 102, 103, or 112 must also be made" (MPEP 2105).

Because the claims recite the combination of "electrodes" and "a single chamber of the heart"/"interventricular septum" the rejection is still deemed proper because the chamber and septum are parts of a living human body. The rejection can be overcome by functionally reciting the electrodes as "adapted to be" implanted in a single chamber of the heart/interventricular septum.

30. In regards to the 35 USC 102(b) rejections of claims 1, 2, 4-12, 18-26, 29-32, 35, 41, 42, and 44, Applicant argued that Cohen does not disclose "stimulating a chamber of the heart at a plurality of locations in the chamber based in the progress of the contraction". This is not moving because Cohen discloses, in claim 1, the plurality of electrodes are connected to the terminal that will produce the "minimum QRS duration" with respect to the electrode locations. Therefore, the stimulation is based on the progress of contraction (QRS complex). Additionally, the abstract of the disclosure clearly describes the claimed subject matter because "determining a progress of contraction" can be interpreted as determining almost any intrinsic activity, which the abstract discloses.

31. Applicant further argued that no mention is made of claim 18 in the body of the previous Office Action text. Because claim 18 is merely a "means for" analog of the method claimed in claim 1, the same grounds of rejection for the method of claim 1 apply to the "means for" performing the method of claim 1 (i.e. claim 18).

32. Applicant further argued that Cohen does not disclose stimulating the left ventricle of the heart at a plurality of locations in the left ventricle. If Applicant considers

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epicardial stimulation or septal stimulation to be "in the left ventricle" as recited in claims 33 and 52, then it follows that the transeptal and epicardial stimulation disclosed by Cohen at column 18, line 47; column 22, line 14 and column 24, line 14 is also "in the left ventricle". Additionally, "transeptal" indicates that Cohen's lead passes through the septum, thus enters the left ventricle.

33. Applicant further argued that Cohen does not disclose stimulating a plurality of locations in the left ventricle. However, Cohen discloses "left ventricular wall contact by electrodes [plural]" in column 18, line 47.

34. In regards to the 35 USC 102/103 rejection of claim 3, Applicant argued that rejections under 102 and 103 are mutually exclusive and the 103(a) rejection is lacking motivation. In regards to the argument that rejections under 102 and 103 are mutually exclusive, a 102/103 rejection is deemed proper if: *"the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention but has basis for shifting the burden of proof to applicant as in In re Fitzgerald, 619 F.2d 67, 205 USPQ 594 (CCPA 1980)."* See MPEP § § 2112- 2112.02. Cohen discloses that the system can be applied to the atrial chambers. This means that, if operation is similar to operation in the ventricles as described on the rest of the disclosure, depolarization signals are sensed from multiple locations within an atrial chamber. It then follows that this is either an implicit anticipatory disclosure of the claimed subject matter, or a suggestion to modify, thus rendering an obviousness rejection proper. Therefore, the 102/103 rejection is deemed proper and stands. In

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response to the lack of motivation to modify Cohen's invention, paragraph 19 of the previous Office Action clearly states that the motivation to provide the modification is to "more vividly sense depolarization of the chamber".

35. The remaining arguments are directed to the alleged lacking element of providing stimulation "in the left ventricle". As addressed above, if Applicant considers epicardial stimulation or septal stimulation to be "in the left ventricle" as recited in claims 33 and 52, then it follows that the transeptal and epicardial stimulation disclosed by Cohen at column 18, line 47; column 22, line 14 and column 24, line 14 is also "in the left ventricle". The species of epicardial and septal placement necessarily anticipate the genus of "in the ventricle". Additionally, "transeptal" indicates that Cohen's lead passes through the septum, thus enters the left ventricle.

Conclusion

36. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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5/24/06

GEORGE R. EVANISKO
PRIMARY EXAMINER
5/25/06